IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD. Plaintiffs, v. LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS INC., WATSON LABORATORIES, INC., APOTEX INC., and APOTEX CORP., Defendants.	Civil Action No. 2:13-cv-121

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO WATSON LABORATORIES, INC.'S, LUPIN PHARMACEUTICALS, INC.'S, APOTEX INC.'S AND APOTEX CORP.'S JOINT MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. RE 44,048

Plaintiffs G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. (collectively, "Pfizer") submit this memorandum in opposition to the joint motion for summary judgment of invalidity of U.S. Patent No. RE44,048 ("the '048 patent") filed by defendants Watson Labs., Inc., Lupin Pharm., Inc., Apotex Inc. and Apotex Corp. (collectively, "Defendants"). The '048 patent is a reissue of U.S. Patent No. 5,760,068 (the "'068 patent").

PRELIMINARY STATEMENT

Pfizer's '048 patent was the product of a rigorous four-year reissue examination process conducted by the United States Patent and Trademark Office ("PTO") that involved the patent examiner and at least three specialists at the PTO. In granting the '048 patent, the PTO concluded that, pursuant to 35 U.S.C. § 251, reissue of Pfizer's '068 patent was appropriate and

Pfizer was entitled to remedy with the '048 patent the defect in the '068 patent that the Federal Circuit had previously identified in invalidating the '068 patent on double patenting grounds.[1] In particular, during the prosecution of the '048 patent, the PTO expressly permitted Pfizer to amend the priority benefit claim in the '068 patent so to identify the '048 patent as a "divisional" of Pfizer's U.S. Patent No. 5,466,823 (the "'823 patent"), rather than a continuation-in-part ("CIP") of the '823 patent.[2] The PTO also concluded that, as amended, the '048 patent is protected, under 35 U.S.C. § 121, from being invalidated on double patenting grounds.[3]

Defendants' motion for summary judgment focuses on the procedural technicalities involved in Pfizer's prosecution of the reissue application that resulted in the issuance of the '048 patent. Defendants ask this Court to reject the PTO's interpretation and application of the relevant statutory provisions, the regulations enacted by the PTO and the PTO's own MPEP. As shown below, however, the issues that Defendants raise were fully vetted

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1 "Obviousness-type double patenting is a judicially created doctrine that 'prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.'" *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008).

2 "A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or 'division.'" MPEP § 201.06 (8th ed. Rev. 9, Aug. 2012). "A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said nonprovisional application." MPEP § 201.08.

3 The § 121 "safe harbor is provided to protect an applicant from losing rights when an application is *divided*." *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010).

and soundly decided by the PTO. Defendants' motion papers rely on bluster, not authority. Accordingly, Defendants' motion for summary judgment of invalidity should be denied.[4]

RESPONSE TO DEFENDANTS' STATEMENT OF UNDISPUTED FACTS

Paragraphs 1-6 of Defendants' Statement of Undisputed Facts are statement of law, not statements of fact.[5] Defendants' summary descriptions of the relevant prosecution histories (¶¶ 7-28, 33-43) and of the prior litigation concerning the '068 patent (¶¶ 29-32) are necessarily incomplete. Pfizer specifically disputes Defendants' Statement of Undisputed Facts as follows:

> 17. PCT '720 was filed in response to a restriction requirement in the original '594 application. *See infra* p. 5.
>
> 19. The filing date of the '113 application is November 14, 1994. 35 U.S.C. § 363; MPEP § 1893.03(b).
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> 22. During prosecution of the '113 application the examiner essentially repeated the restriction requirement that he made during the prosecution of the '594 application. *See infra* p. 5-6; Martin Ex. 4.[6]
>
> 34. The reissue application was filed as a result of the restriction requirement during the prosecution of the '594 application, as was the PCT '720/'113 application. *Infra* POINT III.

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4 In lieu of valid authority, Defendants submit the (unsworn) expert report of John Doll former Commissioner for Patents at the PTO. Pfizer has separately moved to strike Mr. Doll's report as an improper effort to present additional advocacy in the guise of an expert report. (Doc. 178).

5 Pfizer does not "make-believe" that the '048 patent is valid as Defendants insist. (Defendants' Mem. in Supp. of the Joint Mot. for Summ. J. of Invalidity of U.S. Patent No. RE44,048, at 2 ("Defs. Br.")). The patent was duly issued by the PTO following extensive examination and is presumed valid as a matter of law. 35 U.S.C. § 282.

6 "Martin Ex. __" refers herein to exhibits to the declaration of Pfizer's counsel Jeffrey Martin.

THE RELEVANT PROSECUTION HISTORIES

The patent-in-suit, the '048 patent, issued on March 5, 2013, from U.S. application number 12/205,319, filed September 5, 2008 ("the '319 application"). The '048 patent identifies itself as "a reissue of the ['068 patent], which issued from U.S. application Ser. No. 08/648,113 ["the '113 application"] filed on Sep. 6, 1996, which is a 35 USC § 371 National Stage Application of PCT/US 94/12720 ["PCT '720"] filed Nov. 14, 1994, and a divisional of U.S. application Ser. No. 08/160,594 ["the '594 application"] filed Nov. 30, 1993 (now issued as [the '823 patent])." ('048 patent 1:22-27).

The Prosecution of the '594 Application/'823 Patent

Pfizer's predecessor G.D. Searle & Co. filed the '594 application on November 30, 1993. (Mack Decl. Ex. 1). The application, as filed, contained compound claims (claims 1-20), pharmaceutical composition claims (21-26) and method of treatment claims (27-37). On July 12, 1994, the patent examiner issued a restriction requirement that applicants prosecute only one of the three classes of claims in the '594 application. (Martin Ex. 1). The rest of the claims could be prosecuted separately. On September 15, 1994, the applicants elected to prosecute the compound claims in the '594 application. (Amendment & Resp. to Restriction & Election Requirements) (Martin Ex. 2).

The '594 application, as amended, issued as the '823 patent on November 14, 1995. The '823 patent expired on November 30, 2013; the U.S. Food and Drug Administration ("FDA") has extended that exclusivity until May 30, 2014, in light of pediatric testing by Pfizer. (Sorenson Decl. Ex. 16 at WAT-CEL-00021014).

The Prosecution of the '629 Application/'207 Patent

On April 6, 1994, while the '594 application was being prosecuted and prior to the July 1994 restriction requirement, the applicants filed application no. 223,629 ("the '629

application"), a CIP of the '594 application. (Sorenson Decl. Ex. 5 at PFZCEDV_1312769). The '629 application issued on May 28, 1996, as U.S. Patent No. 5,521,207 ("the '207 patent"), containing compound, pharmaceutical composition and method of treatment claims involving a single chemical compound. ('207 patent at 46:36-60) (Mack Decl. Ex. 7).

The Prosecution of the '059 Application/'165 Patent

On June 1, 1995, Pfizer filed application no. 457,059 ("the '059 application") as a divisional of the '594 application. (Martin Ex. 3). As filed, the '059 application contained compound, pharmaceutical composition and method of treatment claims. (*Id.* at 84-118). The application issued as U.S. Patent No. 5,563,165 ("the '165 patent") on October 8, 1996, containing only pharmaceutical composition claims. (Martin Ex. 28). The '165 patent expired on November 30, 2013; the FDA has extended that exclusivity to May 30, 2014.

The Prosecution of the PCT '720/'113 Application/'068 Patent

On November 14, 1994 -- soon after Pfizer's September 14, 1994 election to prosecute the compound claims (rather than the pharmaceutical composition or method of use claims) in the '594 application in light of the July 12, 1994 restriction requirement -- Pfizer filed PCT '720 under the terms of the Patent Cooperation Treaty.[7] (Mack Decl. Ex. 12). The PCT application, as filed, included compound, pharmaceutical composition and method of treatment claims. The method of treatment claims encompassed much of the subject matter claimed in the

[7] The PCT is a multilateral treaty that establishes an international patent application filing system that allows patent applicants to seek protection for their inventions in multiple countries by initially filing a single application. The examination and decision to grant or reject an application takes place in what the U.S. calls the "national stage" in which national substantive patent law applies. (*See* MPEP § 1801) (Bulock Dep. 21; Martin Ex. 30).

method of treatment claims that were restricted out of the '594 application. (Jorgensen Report ¶¶ 53-57)).[8]

PCT '720 is identified on its face as a CIP of the '594 application and a CIP of the '629 application. (Mack Decl. Ex. 12). PCT '720 entered U.S. national stage prosecution on September 6, 1996, as the '113 application, containing compound, pharmaceutical composition and method of treatment claims. Pursuant to 35 U.S.C. § 363, the '113 application had the November 14, 1994 filing date of the PCT '720. *See also* MPEP § 1893.03(b).

On April 8, 1997, applicants amended and added claims and stated: "A lack of unity rejection/restriction requirement between compounds, pharmaceutical compositions and methods of use, was made in a telephone conversation with the Examiner. Applicants elected, with traverse, the method of use claims." (Martin Ex. 4).

The '113 application issued as the '068 patent on June 2, 1998, and, consistent with the July 1994 restriction requirement during the '594 prosecution, the '068 patent contained only method of use claims. The '068 describes itself as a CIP of the '629 application ('207 patent), which is a CIP of the '594 application ('823 patent). (Mack Decl. Ex. 5). The '068 patent expires on June 2, 2015; the FDA has extended the exclusivity until December 2, 2015.

The Prosecution of the '048 Patent-In-Suit

- **The prior Celebrex® patent litigation**

In February 2004, Pfizer sued defendant Teva Pharms. USA, Inc. ("Teva") in the District of New Jersey (the "Teva Litigation") to enforce the '823, '165 and '068 patents and prevent Teva from obtaining FDA approval to market generic copies of Pfizer's Celebrex®

[8] Reference is to the Expert Report of Yale University Chemistry Professor William L. Jorgensen adopted in his accompanying declaration.

product. On March 20, 2007, the district court ruled that Teva had infringed the patents and had "failed to prove by clear and convincing evidence" that the patents were invalid or unenforceable. *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 482 F. Supp. 2d 390, 477 (D.N.J. 2007). The district court stated that it would not consider Teva's argument, raised for the first time in its post-trial brief, that 35 U.S.C. § 121 did not protect the '068 patent from double patenting because the '068 patent was a CIP and not a divisional.[9] *Id.* at 476. However, the court added that "were it to consider Teva's argument it would find that § 121 does apply to the '068 Patent." *Id.* at 476 n.58.

On March 7, 2008, the Federal Circuit affirmed that the '823 and '165 patents were valid and infringed, but found "that the asserted claims of the '068 patent [were] invalid for double patenting." *Pfizer Inc. v. Teva Pharms.*, 518 F.3d 1353, 1367 (Fed. Cir. 2008). The court concluded that "the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications." *Id.* at 1362. The Federal Circuit explained that although the '068 patent was "derived from the application that led to the '823 patent," the '068 patent "was filed as a CIP and not a divisional application." *Id.* The Federal Circuit disagreed with Pfizer's contention "that the term

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[9] 35 U.S.C. § 121 provides:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

'divisional application' as it is used in section 121 refers broadly to any type of continuing application filed as a result of a restriction." *Id.* at 1360.

- **The Reissue Prosecution**

On September 5, 2008, after the Federal Circuit decision, Pfizer filed the '319 application which ultimately issued as the '048 patent. Pfizer filed the application as a reissue application, pursuant to 35 U.S.C. § 251, which then provided in subparagraph (a):

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.[10]

Pfizer was requesting reissue "to correct those errors that prevented the application from which the ['068] patent issued from complying with the definition of a divisional application pursuant to M.P.E.P. 201.06 entitled to protection under 35 U.S.C. § 121 as recently enunciated by the Federal Circuit." (Reissue App. Decl., Supp. 2) (Martin Ex. 6). In support of the '319 application, Pfizer filed a Preliminary Amendment which explained:

> The present reissue application seeks to correct a technical defect in the specification and other errors by taking, *inter alia*, the following action:
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> (1) amending the specification of the '068 Patent to delete all portions not in the earliest priority application (the '594 Application);

[10] Since the filing of the '319 application, the words "without any deceptive intention" have been removed from the statute. The language shown above governs the '048 patent.

> (2) amending the priority benefit claim of the '068 Patent to indicate the divisional application relationship with the '594 Application, and to withdraw the priority claim to U.S. Patent Application Serial No. 08/223,629, filed April 6, 1994, which issued as U.S. Patent No. 5,521,207 (the "'207 Patent"); and
>
> (3) amending the issued claims to limit the compound specified in the claimed methods of treatment to the species [celecoxib].
>
> These actions are being taken so that the '113 Application from which the '068 Patent issued qualifies as a divisional application in compliance with the recent Federal Circuit opinion.

(Mack Decl. Ex. 21, at 35). The Preliminary Amendment described the changes to the priority claim in the '068 patent as follows:

> The present reissue application withdraws the priority claim to U.S. Patent Application Serial No. 08/223,629. The priority claim to the '594 Application is maintained and the divisional status of the '113 is asserted in view of the amendments to the reissue application.

(*Id.* at 44).

The '319 application included a declaration which stated, pursuant to 35 U.S.C. § 251, that the '068 was "wholly or partly inoperative or invalid" "by reason of a defective specification or drawing" and "by reason of other errors." (Martin Ex. 5, at 1). The declaration identified, as "at least one error upon which reissue is based," the fact that, per the Federal Circuit, the '113 application which resulted in the '068 patent "failed to qualify as a divisional application entitled to protection under 35 U.S.C. § 121." (*Id.* at Supp. 2).

On May 12, 2009, the examiner rejected the claims of the '319 application as being obvious under 35 U.S.C. § 103(a). (Martin Ex. 6). On June 26, 2009, applicants opposed the obviousness rejection. On July 30, 2009, the examiner, Kamal Saeed, met with Pfizer patent prosecutors Scott Williams and Philip B. Polster as well as with Daniel Reisner of Kaye Scholer LLP, who had represented Pfizer in the Teva Litigation. (Martin Ex. 8).

The examiner issued a December 3, 2009 Office Action, withdrawing the § 103 rejection, but rejecting the reissue application as improper under § 251, stating:

> A reissue applicant's failure to timely file a divisional application covering the non-elected invention(s) in response to a restriction (or an election of species) requirement is not considered to be error causing a patent granted on the elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Accordingly, this is not correctable by reissue of the original patent under 35 U.S.C. 251.

(Mack Decl. Ex. 23, at 4). The examiner also rejected the claims on double patenting grounds in view of the '165 patent.

On April 22, 2010, Pfizer's patent prosecution counsel, Dean Olson, Philip Polster and Scott Williams, met with Examiner Saeed as well as PTO quality assurance specialists Bennet Celsa and Jean Vollano. (Martin Ex. 29). Celsa was a PTO attorney and reissue expert. (Williams Dep. 255-57, Martin Ex. 9; Olson Dep. 136, Martin Ex. 10).

On May 27, 2010, applicants responded to the December 3, 2009 Office Action, replacing the first paragraph of the specification with the following:

> This application is a reissue of U.S. Pat. No. 5,760,068, which issued from U.S. Application Serial No. 08/648,113 filed on September 6, 1996, which is a 35 USC § 371 National Stage Application of PCT/US 94/12720 filed Nov. 14, 1994, and a divisional of U.S. Application No. 08/160,594 filed Nov. 30, 1993 (now issued as U.S. Pat. No. 5,466,823).

(Martin Ex. 11, at 2).

In a September 22, 2010 "final" rejection, the examiner repeated:

> The reissue oath/declaration filed with this Application was found defective because the error which is relied upon to support the reissue Application is not an error upon which a reissue can be based. See MPEP 1412.02.

(Mack Decl. Ex. 24, at 4).

Pfizer's Dean Olson participated in additional office interviews with Examiner Saeed on October 27, 2010 and March 1, 2011. (Martin Exs. 12, 13). On March 9, 2011, Pfizer filed a Request for Continuing Examination and a further reissue declaration, citing additional errors that were correctable through reissue. Pfizer stated that "the original patent [was] wholly or partly inoperative or invalid" "by reason of a defective specification or drawing," "by reason of the patentee claiming more or less than he had the right to claim in the patent" and "by reason of other errors." (Reissue Application Decl. 1) (Martin Ex. 14). The additional errors included (i) the fact that variables R^2, R^3 and R^4 in the chemical structures depicted in the claims of the '068 patent had "certain incorrect substituents" and (ii) that "claims 2, 3, 7, 8 and 12 list substituents and/or compound names that are not within the scope of the claims from which they depend." (*Id.* at Supp. 2).

On June 7, 2011, Mr. Olson attended another PTO office interview with Examiner Saeed and PTO quality assurance specialists Jean Witz and Jean Vollano. On August 4, 2011, the examiner acknowledged that the applicants' March 2011 declaration had "identified at least one error that is correctable in reissue under 35 U.S.C. § 251." (Martin Ex. 17, at 4). The examiner allowed applicants to "present amendments in [the] reissue case, to correct the error" which had resulted in the invalidation of the '068 patent on obviousness-type double patenting grounds in view of the '165 patent, "by conforming [the '068 patent] to a proper divisional of [the '594 application]." (*Id.*) On that basis, the examiner withdrew the double patenting rejection. (*Id.*) The examiner nonetheless rejected the new claims, requiring that they be supported by a supplemental declaration.

Pfizer filed a third reissue declaration on October 11, 2011, confirming that "[e]very error in the patent which was corrected in the present reissue application and is not

covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the Applicants." (Martin Ex. 18). On December 29, 2011, however, Examiner Saeed again stated that the error relied upon by the applicants was "not an error upon which a reissue can be based." (Martin Ex. 19, at 2). Dean Olson, Examiner Saeed and PTO attorney Celsa held another office interview on February 16, 2012. (Martin Ex. 20).

In a June 6, 2012 Response to the December 29, 2011 Office Action, applicants explained that they had "identified the exact types of 'errors' for which U.S.C. § 251 was enacted to permit correction"; "correction of these errors [is] contemplated by 'liberally' construing the statute in view of its 'remedial . . . nature." (Martin Ex. 21, at 7). Applicants also pointed out that by submitting additional claims 26-30 which were "narrower than original claim 1," applicants had remedied an error that arose from having not filed narrower claims during the prosecution of the '068 patent. (*Id.* at 9).

On or about July 10, 2012, the examiner allowed the '048 patent. Pursuant to 35 U.S.C. § 251, the '048 patent has the expiration date of the '068 patent (June 2, 2015, extended until December 2, 2015).

ARGUMENT

POINT I

THE LAW OF REISSUE

"A reissue application is an application for a patent to take the place of an unexpired patent that is defective as a result of an error in the patent which was made without deceptive intention." MPEP § 201.05. The reissue statute, 35 U.S.C. § 251, "is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally." *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986). The underlying principle is "to

allow correction of those statutory rigors for which the penalty may be excessive under the circumstances." *In re Bennett*, 766 F.2d 524, 527 (Fed. Cir. 1985).

A reissue application is "fully examined in the same manner, and subject to the same rules as if being presented for the first time in an original non-reissue, nonprovisional application." MPEP § 1440. Pursuant to 35 U.S.C. § 252, "every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form." A reissue patent is entitled to the statutory presumption of validity under 35 U.S.C. § 282. *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735, 745 (Fed. Cir. 1993).

POINT II

THE '048 PATENT IS A VALID REISSUE OF THE '068 PATENT

A. The '048 Patent Satisfied the Requirements of 35 U.S.C. § 251

Defendants argue that the '048 patent is not a valid reissue under 35 U.S.C. § 251, on the grounds that (1) failure to file a divisional is not correctable via reissue; and (2) intentional acts are not correctable via reissue. Both assertions by Defendants are half-truths that do not apply here. Neither proposition impairs the validity of the '048 patent. Moreover, Defendants' singular focus on whether Pfizer's prosecution of the '068 patent as a CIP rather than a divisional is a correctable error that justifies reissue under § 251 ignores the fact that Pfizer identified to the PTO additional errors which supported reissue of the '068 patent. Even if the CIP/divisional error was not a basis for reissue, other errors were.

1. Pfizer's Prosecution of Method of Use Claims Restricted Out of the Original '594 Application in a CIP Instead of a Divisional Was a Correctable Error that Supported Reissue.

a. Pfizer's error in prosecuting the '068 patent as a CIP was not "a failure to file a divisional."

Defendants' assertion that a failure to file a divisional application in response to a restriction requirement is not correctable on reissue is based on a series of inapposite cases where the applicant acquiesced in a restriction requirement during prosecution of an original application and then (unlike here) did not file *any* application to pursue claims restricted out of the original application. The applicants in those cases then sought (unlike here) reissue of the original patent to add back claims which had been restricted out. Because the applicant was seeking reissue of the original patent which was not in any way defective and because the claimed error was not made within the four corners of a filed application, but rather in not filing an application, the courts held 35 U.S.C. § 251 inapplicable. Put simply, in those cases, the applicants sought reissue of the original patent, but that patent was not, in the words of § 251, a "patent [that] is, through error deemed wholly or partly inoperative or invalid."[11]

In *Application of Orita*, 550 F.2d 1277 (C.C.P.A. 1977) (Defs. Br. 14), the examiner imposed a restriction requirement with respect to two sets of claims pending in an

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[11] The MPEP's more complete recitation of the tenet upon which Defendants purportedly rely (MPEP § 1402) makes clear that the MPEP's focus is on § 251 requiring an error in a filed application or patent:

> A reissue applicant's failure to timely file a divisional application covering the non-elected invention(s) following a restriction requirement is not considered to be error causing a patent granted on elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Thus, such applicant's error is not correctable by reissue of the original patent under 35 U.S.C. 251.

original application. The applicants elected to pursue one set of claims in the original application but filed nothing to prosecute the non-elected claims. After the original application issued as a patent without the non-elected claims, the applicants sought reissue of the original patent to include the non-elected claims, asserting that they had, in error, "forgotten to timely file a divisional application covering the originally non-elected subject matter." *Id.* at 1279. The court concluded that the applicants' error in failing to file a divisional application did not "cause[ ] the original patent to be 'partially inoperative by reason of the patentee claiming less than he had a right to claim in the patent.'" *Id.* at 1280. The prosecution of the original application was "error-free"; the applicants "claimed exactly what they had a right to claim in the patent, no more nor less, and [the] failure to timely re-file does not change this fact." *Id.*

The *Orita* court also observed that the applicants' proposed use of the reissue statute would render "meaningless" the "co-pendency requirement" in 35 U.S.C. § 120, "for should an applicant fail to file a divisional application while maintaining co-pendency as required by [35 U.S.C.] section 120, he could simply revert to section 251 in order to cure his mistake." *Id.* at 1281.[12]

Similarly, in *In re Watkinson*, 900 F.2d 230 (Fed. Cir. 1990) (Defs. Br. 14), the patent applicant elected to prosecute certain claims in view of a restriction requirement, reserved the right to file a divisional with respect to a non-elected claim and then allowed the original application to issue without filing the divisional. The applicant sought reissue of the original patent to add back the claim that had been restricted out. Applying *Orita*, the court concluded that having acquiesced in the restriction requirement and having then failed to file a timely

[12] Section 120 permits a patent application to claim priority to an earlier application if the application claiming priority is filed before the prior application issued as a patent, *i.e.*, the applications were co-pending.

divisional application, the applicant could not use reissue to undo that forfeiture. The *Watkinson* court pointed out that the *Orita* court had "found that the failure to file a divisional simply cannot be related back as an error in the issued patent. *Id.* at 231.

The decision in *In re Doyle*, 293 F.3d 1355 (Fed. Cir. 2002) (Defs. Br. 14), where reissue was deemed proper, is illuminating. There, the applicants had likewise failed to file further applications to prosecute restricted non-elected claims while the elected claims were being prosecuted in the original application. The applicant sought reissue of the original patent to add broad genus claims which were "neither identical nor substantially similar to the nonelected claims." *Id.* at 1360. The applicant "could have" and "should have" prosecuted the reissue claims "with the elected group, without running afoul of the restriction requirement." *Id.* Hence, there was an "error in the existing patent, namely, failure to claim as broadly as possible matter that could have been sought in the original application." *Id.* at 1361. The court *allowed* reissue of the original patent to include broader claims which could have been prosecuted in the original patent notwithstanding the restriction requirement. Thus, in *Doyle*, reissue of the original patent was appropriate to correct an error made in prosecuting the original patent; the error was not, as in *Orita* and *Watkinson*, a failure to file a further application, which is not, per § 251, an error that renders a patent "wholly or partly inoperative or invalid."

Here, in the case of the '068 patent, Pfizer's error was not in failing to file a separate application to prosecute the method of treatment claims which were restricted out of the original '594 application and Pfizer is not seeking to circumvent the co-pendency requirements of §§ 120-21. As a result of the restriction requirement during the '594 prosecution, Pfizer did file a further application -- PCT '720 which became the '113 application -- that included method of treatment claims encompassing subject matter that had been restricted out of and could not

have been prosecuted in the original '594 application. The PCT '720/'113 application was filed before the '594 application issued as the '823 patent. However, because the patent application containing the non-elected claims was filed as a CIP instead of a divisional, the Federal Circuit held that the method of use claims were invalid for double patenting. Pfizer obtained reissue, not of the original '823 patent, but rather of the PCT '720/'113 application which had proved to be defective in light of the Federal Circuit decision.

In sum, the error here was not an error separate from the patent -- such as the failure to file a timely application -- which would not qualify as a correctable error under § 121. The ultimate failure of the '068 patent to qualify for the safe harbor of § 121, per the decision of the Federal Circuit, was an error made in the drafting and prosecution of the '068 patent. Consequently, the error justified reissue under § 251.

b. In prosecuting the '068 patent, Pfizer did not intentionally surrender the protection afforded by 35 U.S.C. § 121

The term "error," as used in 35 U.S.C. § 251, arises "in a remedial provision designed to advance both the rights of the public and the inventor," and "is to be interpreted . . . in light of Supreme Court decisions favoring the liberal construction of reissue statutes in order to secure to inventors protection for what they have actually invented." *In re Wadlinger*, 496 F.2d 1200, 1207-08 (C.C.P.A. 1974). "The use of the word 'error' in [35 U.S.C. 251] instead of the words 'inadvertence, accident or mistake,' which appeared in the corresponding section . . . of the patent statutes prior to the recodification of 1952, does not involve a substantive change, and the same type of error is necessary to justify a reissue after the enactment of the Patent Act of 1952." *Id.* at 1206. "'Inadvertence' and 'accident' may imply something other than deliberate action, but *'mistake' has a broad sweep and is certainly inclusive of actions taken in full consciousness.*" *Id.* at 1207 (emphasis added). The *Wadlinger*

court added: "The primary definition of 'mistake' is 'to choose wrongly.' (Webster's Seventh New Collegiate Dictionary)."[13] *Id.* "Precedent establishes that for reissue purposes 'error is established where there is no evidence that the appellant intentionally omitted or abandoned the claimed subject matter.'" *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 523 (Fed. Cir. 2012).

Defendants' assertion that "[i]ntentional acts are not correctable via reissue" (Defs. Br. 15) is thus true only where there is a knowing surrender of rights. While it is true that Pfizer's then patent prosecutor, Joseph Bulock, intentionally prosecuted the PCT '720/'113 application as a PCT and not a divisional, Defendants have not shown and cannot show that in doing so Pfizer and Mr. Bulock knowingly chose to forego the protection from double patenting afforded under § 121. To the contrary, Mr. Bulock filed the '113 application expecting that the claims would be protected from double patenting under 35 U.S.C. § 121. (Bulock Dep. 196-97) (Martin Ex. 30). In fact, in the Teva Litigation, the district court expressed the view that the '113 application was protected from double patenting even though it had been filed as a CIP, not a divisional. Only when, on appeal, the Federal Circuit invalidated the asserted claims of the '068 patent on double patenting grounds, based on the court's interpretation of § 121, did it become apparent that the decision to prosecute the method of use claims restricted out of the '594 application together with new matter as a CIP, rather than as a divisional, was an error.[14]

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[13] The *Wadlinger* court also quoted the following dictionary definition of the word "mistake": "Law. Misconception or error of the mind leading a person to do an act which he otherwise would not have done; also the act or omission so arising, as an intentional act or omission arising from ignorance, surprise, imposition or misplaced confidence." 496 F.2d at 1207 n.7.

[14] In *Wadlinger*, the court permitted reissue to take advantage of a "change in the law" which resulted from "case law overruling of case law." 496 F.2d at 1209.

In *In re Serenkin*, 479 F.3d 1359 (Fed. Cir. 2007) (Defs. Br. 15), applicant Serenkin submitted a patent application ("the PCT application") on January 28, 1998, referencing certain drawings that were not included with the application. The applicant submitted the drawings on February 17, 1998. The U.S. Receiving Office under the PCT asked the applicant to decide "whether he preferred to retain the original filing date of January 28, 1998, with the application as filed without drawings or incorporate the drawings as part of the application and accept a new filing date of February 17, 1998." *Id.* at 1361. The Receiving Office "specifically stated" that if the applicant chose the February 17, 1998 date, "the priority date of January 29, 1997 would be lost." *Id.* The applicant then accepted the February 17, 1998 filing date. The application issued as U.S. Patent No. 6,109,425 ("the '425 patent"). *Id.*

The applicant subsequently sought through reissue of the '425 patent to obtain the benefit of the January 29, 1997 filing date. The Federal Circuit held that "the act of choosing a later filing date during prosecution of the PCT application in exchange for inclusion of missing drawings" was not "an 'error' that is correctable under § 251." *Id.* at 1362. The court commented that

> the consequence of losing the January 28, 1998 filing date was not a fact discovered at some later point, but was an issue that was brought to the attention of Serenkin's attorney by [the Receiving Office] at the time of his decision.

Id. at 1363. As the Federal Circuit observed subsequently in *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 523 (Fed. Cir. 2012), the *Serenkin* court "stressed [that] the actions had been taken with knowledge of their consequences."[15]

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[15] *In re Mead*, 581 F.2d 251 (C.C.P.A. 1978) (Defs. Br. 16), is similarly distinguishable. The applicant there had knowingly omitted the subject matter sought to be claimed in the reissue notwithstanding the ramifications of doing so. Furthermore, unlike here, the error (continued...)

Thus, in light of the Federal Circuit opinion in the Teva Litigation, the decision by Pfizer to prosecute the '113 application as a CIP rather than a divisional was correctable on reissue because Pfizer did not intentionally surrender the protection of § 121. In any event, as shown below, Pfizer identified other errors during reissue that were indisputably unintentional and that unquestionably supported reissue pursuant to 35 U.S.C. § 251.

2. Pfizer Identified Additional Errors which Supported Reissue

a. The errors regarding chemical substituents and compound names in the claims of the '048 patent were correctable on reissue.

After the PTO took the position that Pfizer's prosecution of the '113 application as a CIP instead of a divisional was not an error on which reissue could be based, Pfizer identified to the PTO errors in the chemical substituents and compound names which rendered various claims of the '068 patent indefinite in scope and were thus errors upon which reissue could be based. (Resp. Accompanying RCE 5-9, Mar, 10, 2011) (Martin Ex. 15). Defendants do not dispute that the indefiniteness errors identified by Pfizer were a proper basis for reissue. The reissue remedied the errors by eliminating the affected claims. It is clear, therefore, that even if the CIP/divisional error was not a proper basis for reissue, other errors were grounds for reissue.

"Once a proper basis for reissue is asserted, other narrowing changes to the patent's claims can be made without explanation." *Schering Corp. v. Mylan Pharms., Inc.*, 2012 U.S. Dist. LEXIS 59160, at *42 (D.N.J. Apr. 27, 2012); *see also* MPEP 1414.II(B) ("Where more than one error is specified in the oath/declaration and some of the designated 'errors' are found to not be 'errors' under 35 U.S.C. § 251, any remaining error which is an error under 35

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in *Mead* was in the failure to file another application, not in the text of the original patent that was to be changed by reissue.

U.S.C. § 251 will still support the reissue."). Hence, given an error that provided a proper basis for reissue of the '068 patent, Pfizer had the right to correct other errors in the '068 patent -- such as the CIP/divisional error -- as well.

In the context of a reissue patent application, the regulations enacted by the PTO recognize two categories of "errors." Pursuant to the regulations, the supporting declaration must identify an error that triggers reissue, stating as follows:

> (1) The applicant believes the original patent to be wholly or partly inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than the patentee had the right to claim in the patent, stating at least one error being relied upon as the basis for reissue; and
>
> (2) All errors being corrected in the reissue application up to the time of filing of the oath or declaration under this paragraph arose without any deceptive intention on the part of the applicant.

37 C.F.R. § 1.175(a). Thus, 37 C.F.R. § 1.175(a) "requires the patentee to disclose only a single error for correction and to include only a general statement that the errors involved no deceptive intent." *Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1358 (Fed. Cir. 2001).

The PTO regulations contemplate a second category of error which need not satisfy 35 U.S.C. § 251:

> (b)(1) For any error corrected, which is not covered by the oath or declaration submitted under paragraph (a) of this section, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant.

37 C.F.R. § 1.175(b). The Regulations add the following with respect to declarations submitted pursuant to subparagraph (b):

> (c) Having once stated an error upon which the reissue is based, as set forth in paragraph (a)(1), unless all errors previously stated in the oath or declaration are no longer being corrected, a subsequent oath or declaration under paragraph (b) of this section need not specifically identify any other error or errors being corrected.

37 C.F.R. § 1.175(c).

Defendants point to no authority supporting their contention that even if reissue was proper in light of the errors that rendered claims of the '068 patent indefinite, Pfizer would still be precluded from amending the '068 patent to make the reissue patent a divisional.

b. Reissue was also proper to narrow the claims of the '068 patent.

It is well established that a reissue application pursuant to 35 U.S.C. § 251 may be used to narrow the claims of the subject patent. In *In re Tanaka*, 640 F.3d 1246, 1250 (Fed. Cir. 2011), the court held that "adding a dependent claim as a hedge against possible invalidity is a proper reason to seek reissue." Consequently, the lack of narrow claims in the '068 patent -- which was remedied in the '048 patent -- also provided a basis for reissue under § 251.

POINT III

THE DESIGNATION OF THE REISSUE APPLICATION AS A "DIVISIONAL" WAS PROPER

A. The '048 Patent Qualifies As a Divisional of the '594 Application

The '319 application, which amended the '113 application to delete the matter added to the '594 application and to conform the '113 application to a divisional of the '594 application, satisfies the definition of "divisional" set forth in MPEP § 201.06. The claims of the reissue patent were carved out of the '594 patent while the '594 application was pending and the reissue patent contains and claims only subject matter disclosed and claimed in the '594 application. Thus, the face of the '048 patent identifies the patent as a "division" of the '594 application/'823 patent. Contrary to Defendants' assertion, there is nothing -- no statute in 35 U.S.C., no patent rule under 37 C.F.R., and no guideline in the MPEP -- that precludes a national stage application of a PCT application, examined in the PTO under U.S. practice, from being

accurately designated a divisional application per 35 U.S.C. § 121. As Defendants themselves state: the "substance of an application controls its priority." (Defs. Br. 18).

The law is clear that a national stage application can be a divisional of a prior U.S. national application. Indeed, a national stage application can claim priority under § 120 to a prior U.S. national application. MPEP § 1893.03(c) specifically states that

> [a] national stage application may include a benefit claim under 35 U.S.C. 119 (e), *or 120* and 365 (c) *to a prior U.S. national application or under 35 U.S.C. 120* and 365 (c) to a prior international application designating the U.S. The conditions for according benefit under 35 U.S.C. 120 are as described in MPEP § 201.07, § 201.08, and § 201.11 and are similar regardless of whether the U.S. national application is a national stage application submitted under 35 U.S.C. 371 or a national application filed under 35 U.S.C. 111(a).

MPEP § 1893.03(c) (emphasis added).

Defendants assert that the reissue application cannot be both a § 371 application claiming the benefit of the filing date of the PCT '720 application and a § 111(a) application claiming to be a divisional of the '594 application. This argument is a red herring. When PCT '720 entered the U.S. national stage as the '113 application, the application became a U.S. national application and was no different than any other U.S. national application (other than the difference between unity of invention and restriction practices). The relevance of the '068 patent having originated as a PCT application is limited to the fact that the filing date of the '113 application is the PCT filing date.

"Once the national stage application has been taken up by the examiner, prosecution proceeds in the same manner as for a domestic application with the exceptions that: (A) the international filing date . . . is the date to keep in mind when searching the prior art; and (B) the unity of invention proceeds as under 37 C.F.R. 1.475." MPEP § 1893.03. Plainly, during ordinary patent prosecution, claims of priority may be amended. Under 35 U.S.C. § 120,

a patent application may be entitled to claim priority to an earlier co-pending application if the application claiming priority "contains or *is amended* to contain a specific reference to the earlier filed application." (Emphasis added).

The PTO regulations specify the information that must be added by amendment to claim priority. 37 C.F.R. § 1.78 (a)(2) provides that "any . . . application . . . claiming the benefit of one or more prior-filed copending . . . applications . . . must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number." *See Hyatt v. Kappos*, 625 F.3d 1320, 1323 (Fed. Cir. 2010) ("As filed the '702 application . . . originally claimed priority through a chain of related applications to an application filed in 1984 and was later amended to claim priority to a 1975 application."); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1367 (Fed. Cir. 2001) (during prosecution the applicant amended the application which claimed priority to a particular patent to reflect that the application was a continuation-in-part of that patent); *Nissim Corp. v. Time Warner, Inc.*, 2011 Pat. App. LEXIS 23150, at *11-12 (B.P.A.I. Oct. 27, 2011) (during prosecution the applicant "amended the continuity status of [the] application" stating that the application "is a divisional and not a continuation-in-part of prior application 07/832,335").

The case law makes clear that on reissue the PTO can and does change claims of priority made in the patent which is the subject of the reissue. *See Fontijn v. Okamoto*, 518 F.2d 610, 621 (C.C.P.A. 1975), ("a reissue application filed for the sole purpose of perfecting a claim to priority . . . is not in contravention of the requirements of section 251"); *Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 714 (Fed. Cir. 2008) (priority claim in a reissue patent was amended to "claim priority, through several applications, as a continuation-in-part, . . . to the 1988 application," instead of claiming priority as a continuation of a 1992 application); MPEP §

1402 ("The most common bases for filing a reissue application are . . . (D) applicant failed to make reference to or incorrectly made reference to prior copending applications").

Accordingly, as a patent issuing from a U.S. national application, the '048 patent is entitled to claim priority as a divisional application of the '594 application under § 121. There is nothing in the patent laws or regulations that preclude the '048 patent from being a divisional of the '594 application. Defendants have not shown otherwise.

B. The '113 and '319 Applications Were Co-Pending with the '594 Application

Pursuant to 35 U.S.C. § 121, in order to be protected from double patenting in light of the '823 patent or the '165 patent, the application for the '068 patent had to be filed before the '823 patent issued on November 14, 1995. The filing date of a national stage application is the filing date of the international application. As MPEP § 1893.03(b) states,

> An international application designating the U.S. has two stages (international and national) with the filing date being the same in both stages. Often the date of entry into the national stage is confused with the filing date. It should be borne in mind that the filing date of the international stage application is also the filing date for the national stage application.

Accord Broad. Innovation, LLC v. Charter Commc'ns, Inc., 420 F.3d 1364, 1368 (Fed. Cir. 2005). Accordingly, the filing date of the '068 patent was November 14, 1994, the filing date of PCT '720, not the May 21, 1996 date on which the '113 application papers were deposited with the PTO. Therefore, the '048 patent supplants a patent which issued from an application that was co-pending with its parent application, *i.e.*, the '594 application ('823 patent).

Thus, contrary to Defendants' assertion (Defs. Br. 18), the '048 patent does not have two filing dates. The actual filing date of the '113 application is the PCT filing date. Pursuant to 35 U.S.C. § 121, a divisional has the "benefit of the filing date" of the original

application. The filing date of the original application is the *effective* filing date of the divisional, 35 U.S.C. § 100(i)(1)(B), not the actual filing date.

C. The Application For The '068 Patent and the Reissue Were Filed "As A Result" Of The Restriction Requirement Imposed During The Prosecution Of The '594 Application

"[W]hen the existence of multiple patents is due to the administrative requirements imposed by the Patent and Trademark Office, 35 U.S.C. § 121 provides that the inventor shall not be prejudiced by having complied with those requirements." *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996). Section 121 "provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issued therefrom)." *Pfizer*, 518 F.3d at 1360.

Clearly, the '113 application which yielded the '068 patent was filed "as a result" of the July 7, 1994 restriction requirement during the prosecution of the parent '594 application. Pursuant to that restriction requirement, Pfizer chose in September 1994 to pursue compound claims -- but not pharmaceutical composition or method of treatment claims -- in the '594 application. As a consequence of that election, the non-elected pharmaceutical composition and method of use claims were "withdrawn from further consideration by the examiner." 37 C.F.R. § 1.142(b).

Absent the restriction requirement, the claims of the '068 patent, all of which are method of treatment claims, would have been prosecuted as part of the parent '594 application. Instead, the method of treatment claims, which were restricted out of the '594 application, had to be and were prosecuted separately. Thus, as a result of the restriction requirement, the PCT application, which was filed on November 14, 1994, and became the '113 application and ultimately the '068 patent encompassed claims to a method of treating inflammation with

celecoxib.[16] When the '068 patent was invalidated, Pfizer corrected its error in prosecuting the '068 patent as a CIP rather than a divisional and prosecuted in the '319 application ('048 patent) method of use claims which, but for the restriction requirement in the '594 prosecution, would have been prosecuted in that original application.[17]

Defendants' reliance (Defs. Br. 27) on *Bristol-Myers Squibb Co. v. Pharmchemie, B.V.*, 361 F.3d 1343 (Fed. Cir. 2004), is misplaced. The court there rejected the patentee's argument that the patent-in-suit was the result of a 1973 restriction requirement in a predecessor application and could not have been prosecuted together with the claims of the reference patent which was being cited as invalidating the patent-in-suit on double patenting grounds. The court held that the 1973 restriction requirement was not in effect and did not prevent the patent-in-suit claims and the reference patent claims from being prosecuted together in light of a subsequent restriction requirement which was "different from, and inconsistent with, the 1973 restriction requirement." *Id.* at 1349.

Here, by contrast, there was no subsequent restriction requirement inconsistent with the restriction requirement imposed during the prosecution of the '823 patent and there is no grounds for concluding that the claims of the '068 patent could have been prosecuted together with the claims of the '165 patent.

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16 The fact that PCT '720 claimed priority to not only the '594 application but also to the '629 application does not in any way change the fact that, at least in part, the PCT '720/'113 application was filed as a result of the restriction requirement.

17 The fact that PCT '720 and the '113 application contained not only non-elected (for prosecution in the '594 application) method of use claims, but also non-elected pharmaceutical composition claims and elected compound claims, does not preclude those applications from having been filed "as a result" of the restriction requirement. *See Boehringer*, 592 F.3d 1340, 1344 (divisionals filed as a result of restriction requirement "originally contained all of the claims of the original . . . application" from which they were divided).

D. The '629 Application/'207 Patent Is Irrelevant

Defendants err in insisting that the '629 application/'207 patent somehow prevents the '048 patent from being denominated a divisional of the '594 application. The '048 patent issued from an application, *i.e.*, the '113 application, that was the national stage of the PCT '720 application which claimed separately to be a direct CIP of the '594 application and a direct CIP of the '629 application. The reissue prosecution did not and could not change the PCT application. The reissue application and the '048 patent merely claims the benefit of the fact that PCT '720 was a direct CIP of the '594 application, but does not claim the benefit of the fact that the PCT was a CIP of the '629 patent.

Moreover, the reissue application withdrew the '113 application's claim of priority to the '629 application which in turn claimed priority to the '594 application and instead directly claimed priority to the '594 application as a divisional. As set forth above, reissue is appropriate to change the priority claim of the patent being reissued. *See Fontijn v. Okamoto*, 518 F.2d 610 (C.C.P.A. 1975). Unlike the '629, PCT '720 and '113 applications, the '319 reissue application did not contain new matter that was not contained in the original '594 application. Accordingly, the '319 application appropriately claimed to be a divisional of the '594 application. As discussed above, there is nothing under the U.S. patent laws and regulations which preclude a national stage application from being a divisional of another U.S. application. As a result of the changes made to the '113 application during reissue, the '319 application qualifies as a divisional.

E. There Is No Evidence That Pfizer Filed PCT '720 To Extend The '068 Patent

Defendants cite no evidence that Pfizer filed the application that resulted in the '068 patent in order to extend the term of the '068 patent. In fact, the prosecutor's testimony was

to the contrary.[18] Moreover, Defendants rely on the false premise that if Pfizer had filed the application for the '068 patent as a divisional, the application would not have been filed until the May 21, 1996 national stage entry date of the '113 application and would have expired on November 30, 2013, twenty years from the filing date of the '594 application, instead of expiring 17 years from issuance, on June 2, 2015. In fact, if Pfizer had filed the '113 application as a divisional on the November 14, 1994 filing date of the PCT '720, the resulting patent would have expired 17 years from issuance. In fact, the same rules for calculating the patent term applied to the '823, '165 and '068 patents.

Finally, the language of § 251 is mandatory, not discretionary: "the Director shall . . . reissue the patent." Therefore, Pfizer is entitled to the benefits afforded by the reissue statute regardless of why Pfizer filed the '113 application as a PCT.

POINT IV

THE COURT SHOULD GIVE DEFERENCE TO THE PTO

Given that Defendants' motion concerns the technical procedural details of prosecuting reissue applications this Court should give deference to the PTO's reading and application of 35 U.S.C. §§ 251 and 121 as well as the PTO's interpretation and application of its regulations and its MPEP.

Pursuant to 35 U.S.C. § 2(b)(2)(A), the PTO "may establish regulations, not inconsistent with law which shall govern the conduct of proceedings in the Office." "Because the Patent Office is specifically charged with administering statutory provisions relating to 'the

[18] Mr. Bulock testified that Searle (Pfizer's predecessor) generally used the PCT application "as a cost effective way to foreign file in multiple jurisdictions." (Bulock Dep. 61) (Martin Ex. 30). Mr. Bulock rejected the notion that Searle filed a PCT application to delay the prosecution. (*Id*. at 62).

conduct of proceedings in the office, 35 U.S.C. § 2(b)(2)(A), we give *Chevron*[19] deference to its interpretations of these provisions." *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1337 (Fed. Cir. 2008).

"[C]ourts have shown a similar degree of deference to agency decisions in reviewing the MPEP as they have when reviewing more formal rules under the doctrine announced in *Chevron* . . ., seeing their task as determining 'whether the rule or procedure is within the agency's statutory authority and is reasonably related to the purposes of the enabling legislation . . . and does no violence to due process.'" *Fressola v. Manbeck*, C.A. No. 92-0939, 1995 U.S. Dist. LEXIS 9116, at *5-6, (D.D.C. Mar. 30, 1995). The PTO's interpretation of its own regulations -- such as 37 C.F.R. § 1.175 -- also deserves deference. *See Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945).

CONCLUSION

Based on the foregoing, Defendants' motion for summary judgment of invalidity should be denied.

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Respectfully submitted,

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[19] Reference is to the Supreme Court decision in *Chevron U.S.A. v. Natural Res. Def. Council Inc.*, 467 U.S. 837 (1984).

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